



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,417	10/31/2003	Shivkumar Mahadevan	VTN 5023	2097
27777	7590	06/13/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			DRODGE, JOSEPH W	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,417

Applicant(s)

MAHADEVAN ET AL.

Examiner

Joseph W. Drodge

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1723

Claims 1-11,13,15-18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In each of claims 1 and 20, recitation in line 2 of "silicone-containing monomer" or "...copolymer or macromer" is inconsistent with "said at least one silicone-containing compound" appearing at the end of the claim.

Also, in claim 1, the description of what "R7...that can under free radical and/or ionic polymerization..." is non-idiomatic and confusing, apparently text has been inadvertently omitted.

Claim 13 improperly depends from canceled claim 12.

Claims 17,18 and 21 are objected to because of the following informalities: Since no claim 16 is present with the claims being considered, claims 17,18 and new claim 21 are misnumbered. It is suggested that any response to this Office Action include a renumbering of the claims. Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1723

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4,10,11,13,15,17,18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kunzler et al PG PUBS Document US2004/0176628 or Bawa et al patent 6,071,439, taken in view of Maiden et al patent 6,367,929 and one or more of the group of patents encompassing Nicholson et al patent 5,760,100, Spinelli et al patent 5,371,147, Spinelli patent 5,019,628 and Spinelli patent 4,810,756, and if necessary, in view of Pilat et al patent 2,188,013.

The claimed term "silicone-containing monomer" has been interpreted to actually encompass copolymers containing multiple polymerizable groups and plural monomers or monomeric groups and to encompass completed intraocular lenses and other medical devices comprised of such "monomer" as discussed on page 2, lines 1-18 and page 4, lines 23-27 of the Instant Specification.

Kunzler et al disclose removal of an impurity phase from silicone using supercritical fluid (paragraph 2, etc.). Carbon dioxide is employed (page 1, 2nd column) per claims 2 and 3. The solvent extraction is conducted within a pressurized vessel which results in corresponding increases in density of the carbon dioxide and extracted solute (portion of paragraph 6 on the 2nd column of page 1 and discussion of examples 1 and 2 on page 2. At the end of the solvent extraction, pressures, hence inherently densities of the solution are suggested as decreased to separate the phases, as Examples 1 and 2 disclose discontinuing the flow of carbon dioxide and depressurizing the vessel. Recitations of densities, temperatures and pressures of claims 4, 10 and 11 are substantially inherent properties of supercritical carbon dioxide and also discussed in paragraph 6 and the Examples. There is a suggestion of at least 2 stages of treatment having varied temperatures and pressures (page 1, 2nd column, paragraph 6 and page 2, paragraph 18) per claims 5-9. Prepolymer monomers or oligomers are treated at paragraph 4 per claim and 13. The recited temperatures and pressures of claim 11 are given at paragraphs 6 and in the Examples.

Bawa et al disclose removal of impurities from manufacture of silicone-containing polymers and other polymers used in the manufacture of contact lenses by solvent extraction with carbon dioxide in the supercritical state (column 1, line 60-column 2, lines 58). The extraction may be incorporated into any manufacturing step of the process of making the contact lenses (column 4, lines 23-32 and 62-68 and column 5, lines 13-16). The extraction is conducted under conditions of high temperature and

Art Unit: 1723

high pressure, hence high density, in a closed chamber (column 7, lines 8-20), and afterwards purged when densities and pressures are suggested as returning to lower ambient conditions.

The claims all differ from Bawa et al or Kunzler in the particular silicone monomers and polymers recited. Generally, various acrylic star monomers and co-polymers are claimed. However, Bawa et al disclose applying of the process to any conventional silicone monomers (column 3, lines 4-49) or to any lens-forming material (column 5, lines 3-13, while Kunzler also is applicable to any commercial silicone monomer process (paragraph 4). Now, Maiden teaches solvent extraction of impurities from silicone polymeric gel mixtures that comprise siloxanes and acrylic acid monomers by varied organic solvents during the manufacture of contact lenses (column 4, lines 42-62, column 5, lines 52-57 and column 8, lines 7-27). Each of the Spinelli '756, '628 and '147 patents and Nicholson teach employ of the recited acrylic star monomers and co-polymers in the manufacture of contact lenses (see the respective Summary of the Invention portions of texts). It would have been obvious to one of ordinary skill in the art to have selected the claimed acrylic star monomers and co-polymers taught by Spinelli '756, '628, or '147 or Nicholson, in the manufacture of the contact lenses of Kunzler et al and purified them as taught by Maiden, to result in contact lens products having favorable characteristics such as improved oxygen permeability, toughness and strength.

The claims may optionally be considered to further differ in requiring the separation of two phases resulting from the solvent extraction to explicitly be caused by

Art Unit: 1723

a lowering of density of the extractant. However, Pilat teaches to separate impurities from high molecular weight oily or other petrochemical or hydrocarbon mixtures by carbon dioxide so as to lower the density of the mixture to separate the mixture into two liquid phases (page 1 from line 36 of column 1 to line 25 of column 2), with the impurities further separated into separate fractions by varying the pressures and temperatures, and hence the densities of the extraction in a series of sequential stages (page 2 from line 45 of column 1 to line 17 of column 2). If necessary, it would have been further obvious to one of ordinary skill in the art to have operated the Kunzler et al or Bawa et al solvent extraction process by effecting separation of purified silicone polymer from the undesired impurities, as taught by Pilat, to fractionate the varied, different contaminants of the mixture being separated, so as to result in a more complete separation and purification of the polymeric mixture.

For compositions containing the particular siloxane monomers of claims 17 and 18, see in particular Nicholson at columns 28,36 and 38, especially column 28, lines 27-52, which depicts siloxane monomers as imparting especially high oxygen permeability to the contact lenses being manufactured.

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kunzler et al PG PUBS Document US2004/0176628 or Bawa et al patent 6,071,439 taken in view of Maiden et al patent 6,367,929 and one or more of the group of patents encompassing Nicholson et al patent 5,760,100, Spinelli et al patent 5,371,147, Spinelli patent 5,019,628 and Spinelli patent 4,810,756 as applied to claim 1

Art Unit: 1723

above, and further in view of Pilat et al patent 2,188,013. Claims 5-9 further differ in requiring the solvent extraction to be conducted in two or more stages with the density of the supercritical carbon dioxide being lowered in second and subsequent stages. However, Pilat teaches to separate impurities from high molecular weight oily or other petrochemical or hydrocarbon mixtures by carbon dioxide so as to lower the density of the mixture to separate the mixture into two liquid phases (page 1 from line 36 of column 1 to line 25 of column 2), with the impurities further separated into separate fractions by varying the pressures and temperatures, and hence the densities of the extraction in a series of sequential stages (page 2 from line 45 of column 1 to line 17 of column 2). It would have been further obvious to one of ordinary skill in the art to have operated the Kunzler et al or Bawa et al solvent extraction process in successive stages having varied temperatures, pressures and densities, as taught by Pilat, to fractionate the varied, different contaminants of the mixture being separated to result in a more complete separation and purification of the polymeric mixture.

Applicant's arguments with respect to claims 1-11,13,15,17,18 and 21 have been considered but are moot in view of the new ground(s) of rejection, however are responded to as applicable to the modified grounds of rejection.

It is argued that neither Bawa et al or Kunzler et al are directed to purification of "raw materials" by solvent extraction, rather than to purification of formed contact lenses. It is submitted that the claims do not specify at what stage of processing of monomers and co-polymers containing the monomers into contact lenses are contacted by a supercritical extraction fluid. It is unclear what is meant by the terminology "raw material" of the arguments. The instant Specification at page 2, lines 1-18 clarifies that the claimed term "silicone-containing monomer" actually encompasses copolymers containing multiple polymerizable groups and plural monomers or monomeric groups and encompasses completed intraocular lenses and other medical devices comprised of such "monomer".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is

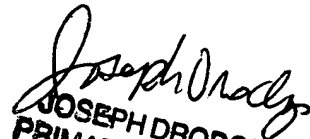
Art Unit: 1723

571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

May 30, 2006


JOSEPH DRODGE
PRIMARY EXAMINER